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| 10/577,887 | 11/22/2006 | Bahaa Botros Seedhom | 7881.15 | 2241 |
| 21599 77590 7752099 KIRTON AND MCCONKIE 60 EAST SOUTH TEMPLE, SUITE 1800 SALT LAKE CITY, UT 84111 | | | EXAMINER | |
| | | | WAGGLE, JR, LARRY E | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/577,887 SEEDHOM ET AL. Office Action Summary Examiner Art Unit Larry E. Waggle, Jr. 3775 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 11/22/2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-13 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-13 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 04/28/2006 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 11/22/2006

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "cylindrical guard," as in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3" has been used to designate both "bone" and a "block."

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 25, 27 and 29, as shown in Figure 3; and 45a, as shown in Figure 11.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes" etc.

Note: The abstract contains well over 150 words.

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Specification

Content of the Specification

- (a) <u>Title of the Invention</u>: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) <u>Cross-References to Related Applications</u>: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement Regarding Federally Sponsored Research and Development</u>: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) <u>Background of the Invention</u>: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) <u>Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98</u>: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is

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separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) <u>Brief Description of the Several Views of the Drawing(s)</u>: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) <u>Detailed Description of the Invention</u>: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

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 Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Note: The content of the specification is not formatted as mentioned above. It should include the headings as mentioned.

The disclosure is objected to because of the following informalities:

On page 3, line 15; page 4, lines 26, 27, 29 and 30; page 5, lines 1, 4, 7, 9, 13, 15 and 21, the term "centraliser" should read "centralizer."

On page 4, lines 16 and 18, the term "centralising" should read "centralizing."

Appropriate correction is required.

Claim Objections

Claim 3 is objected to because of the following informality: It appears in lines 2-3, the phrase "and thereby define the pad-receiving recess" should read "and thereby defining the pad-receiving recess." Appropriate correction is required.

Claim 7 is objected to because of the following informalities: In lines 5 and 10, the term "centralising" should read "centralizing." In line 6, the term "centre" should read "center." In line 8, the term "biassing" should read "biasing." Appropriate correction is required.

Claim 10 is objected to because of the following informality: In line 2, the term "centralising" should read "centralizing." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 recite the limitation "a flange integrally, or removably at an entry end." This limitation is unclear. For examination purposes, the phrase will be treated as reading "a flange integral, or removable at an entry end."

Claim 4 recites the limitation "the removable abutment" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States,

Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarborough et al. (US Patent 5928238).

Scarborough et al. disclose a bone site preparation device (Figure 19) comprising a reamer (40) having cutting teeth at one end and being coupled to a power tool (20) at the other end; a centralizing device (322, 330, 332 and 44) housed within the reamer and having a pointed end (44); and means (330) biasing the pointed end axially outwardly of the reamer to engage with the bone whereby a surgeon may operate the device via one hand by simultaneously maintaining the centralizing device

engaged with the bone while cutting the annular groove with the reamer (Figures 7 and 19-23 and column 6, line 40 – column 7, line 47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pullan et al. (WO 01/39694 A2) in view of Hart et al. (US Patent 6017348).

Pullan et al. disclose an introducer tool (Figure 13) and a method of implanting a repair kit on a prepared bone site from which damaged tissue has been removed, and which a groove into the bone has been formed comprising a bio-compatible pad (9) to fit on a prepared bone site, and an overlying cover sheet (11) to fit in a groove (7), and in

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which the tool comprises; a retaining ring (Figure 13); a pusher (37) having a delivery end (i.e. end towards surgical site) engageable with the cover sheet so as to move a main portion of the cover sheet towards the bone site with the outer portion of the cover sheet trailing behind the main portion (Figure 13); and a pad-receiving recess defined at the delivery end of the pusher when the pusher is relatively adjusted to a pad-implantation position, so that a pad can be introduced into the recess so as to overlie the main portion of the cover sheet (Figure 13), in which the internal arrangement the pusher is such that the pusher engages the trailing portion of the cover sheet to introduce the trailing portion into the groove while the pad engages the bone site and thereby to anchor the pad in position (i.e. the end product being Figure 1).

Pullan et al. disclose the claimed invention except for an introducer cylinder having a hollow driving head at one end for introducing an outer portion of the cover sheet into the groove and a flange integral or removable at the entry end against which the cover sheet is located prior to insertion of the plunger into the cylinder; the plunger being relatively slidable within the cylinder; and a pad-receiving recess defined between the delivery end of the plunger and the inner wall of the cylinder; and a means for limiting the movement of the plunger within the cylinder thereby defining the pad-receiving recess, in which the internal arrangement of the cylinder and the plunger is such that relative withdrawal of the driving head of the cylinder, followed by relative advancing movement, allows the driving head to engage the trailing portion of the cover sheet. Hart et al. teach a bone plug emplacement tool (80) comprising an introducer cylinder (82) having a hollow driving head (88) at one end and a flange (83) at the other;

a plunger (94) being relatively slidable within the cylinder; and a plug receiving recess (i.e. end of cylinder containing the bone plug (78)) defined between the delivery end of the plunger and the inner wall of the cylinder; and a means (90) for limiting the movement of the plunger within the cylinder thereby defining the pad-receiving recess. wherein the flange is capable of supporting the cover sheet prior to insertion of the plunger and the internal arrangement of the cylinder and the plunger is such that relative withdrawal of the driving head of the cylinder, followed by relative advancing movement, would allow for the capability of the driving head to engage the trailing portion of the cover sheet (Figures 6 and 7 and column 6, line 56 - column 8, line 20). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Pullan et al. with the bone plug emplacement tool comprising an introducer cylinder having a hollow driving head at one end and a flange at the other; a plunger being relatively slidable within the cylinder; and a plug receiving recess defined between the delivery end of the plunger and the inner wall of the cylinder and a means for limiting the movement of the plunger within the cylinder thereby defining the pad-receiving recess, wherein the flange is capable of supporting the cover sheet prior to insertion of the plunger and the internal arrangement of the cylinder and the plunger is such that relative withdrawal of the driving head of the cylinder, followed by relative advancing movement, would allow for the capability of the driving head to engage the trailing portion of the cover sheet in view of Hart et al. in order to facilitate repairing an articular cartilage defect by precisely implanting a bone plug and cover sheet using an introducer and plunger.

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Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pullan et al. (WO 01/39694 A2) in view of Hart et al. (US Patent 6017348) in further view of Sample (US Patent 2237450).

Pullan et al. in view of Hart et al. disclose the claimed invention except for a retaining pin receivable by a transverse hole in the plunger and engageable with the flange in order to limit the movement of the plunger within the cylinder. Sample teaches a reamer (Figure 2) and an inner member (Figure 3) comprising a retaining pin (21) receivable by a transverse hole (20) in the inner member and engageable with a recess (12) in the reamer (Figures 1-3 and page 1, column 2, line 48 - page 2, column 2, line 39). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Pullan et al. in view of Hart et al. with the reamer and an inner member comprising a retaining pin receivable by a transverse hole in the inner member and engageable with a recess in the reamer in view of Sample in order to limit the movement of the plunger relative to the reamer.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pullan et al. (WO 01/39694 A2) in view of Hart et al. (US Patent 6017348) in further view of Pandey et al. (US Design Patent D411308).

Pullan et al. in view of Hart et al. disclose the claimed invention except for a padloading block having a number of cells each arranged to receive at least one pad, the block being co-operable with the plunger to allow the plunger to be loaded with at least one pad. Pandey et al. teach a multi-well plate capable of receiving at least one pad and co-operating with the plunger to allow the plunger to be loaded with at least one

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pad (Figure 2). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Pullan et al. in view of Hart et al. with the multi-well plate capable of receiving at least one pad and co-operating with the plunger to allow the plunger to be loaded with at least one pad in view of Pandey et al. in order to allow for a more efficient way to grab preformed pads prior to implantation.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pullan et al. (WO 01/39694 A2) in view of Hart et al. (US Patent 6017348) in further view of Pandey et al. (US Design Patent D411308) and in further view of Scarborough et al. (US Patent 5928238).

Pullan et al. in view of Hart et al. in further view of Pandey et al. disclose the claimed invention except for the plunger having a projecting pin to facilitate removal of a pad from the block. Scarborough et al. teach a drill guide member (44) comprising a pointed tip extending therefrom (Figure 23) to facilitate removal of a bone dowel (D). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Pullan et al. in view of Hart et al. in further view of Pandey et al. with the guide member comprising a pointed tip extending therefrom in view of Scarborough et al. in order to facilitate removing a pad from the block.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough et al. (US Patent 5928238) in view of Spranza. III (US Patent 6884245).

Scarborough et al. disclose the claimed invention except for a debris channel formed at one end of the reamer to allow bone fragments formed by the teeth to escape while the annular groove is being formed. Spranza, III teach a reamer (Figure 2)

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comprising a debris channel (15) (column 3, lines 38-50). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Scarborough et al. with the reamer comprising a debris channel in view of Spranza, III in order to facilitate clearing the bone chip fragment formed by the cutting teeth from the groove.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough et al. (US Patent 5928238) in view of Elias et al. (US Patent 5324300).

Scarborough et al. disclose the claimed invention except for a cylindrical guard and a cylindrical cutting tool which can inter-fit with the reamer to be rotatable relative to the reamer, rotatable by the guard in which the guard is capable to being received by the groove while the cutting tool removes damaged tissue surrounded by the groove. Elias et al. teach a cylindrical guard (124 and 126) and a cylindrical cutting tool (distal end of 124) which can inter-fit with and be rotated relative to a reamer (120), rotatable by the guard in which the guard is capable to being received by the groove while the cutting tool removes damaged tissue surrounded by the groove (Figure 10 and column 7, lines 19-33). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Scarborough et al. with the cylindrical guard and a cylindrical cutting tool which can inter-fit with and be rotated relative to a reamer, rotatable by the guard in which the guard is capable to being received by the groove while the cutting tool removes damaged tissue surrounded by the groove in view of Elias et al. in order to more precisely cut the tissue surrounding

the groove once the reamer has cut the majority of the tissue and allow the guard to be left in place in the event the reamer needs removed prior to ending the operation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is 571-270-7110. The examiner can normally be reached on Monday through Thursday, 6:30am to 5pm, EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Larry E Waggle, Jr/ Examiner, Art Unit 3775 /Thomas C. Barrett/ Supervisory Patent Examiner, Art Unit 3775